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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,441	11/19/2003	J. Donald Hill	018880.0147	3943

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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
11/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/715,441	HILL ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-19,22 and 34-36* is/are pending in the application.

4a) Of the above claim(s) *34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-19,22,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/24/2008 has been entered.

2. Claims 13-19, 22, and 34-36 are pending. Claim 34 is withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al. (US 6,371,965; "Gifford") in view of Berg et al. (US 6,074,416). Gifford discloses a method for delivering a coupler into a blood vessel, the coupler comprising a fixed saddle (167; fig. 9-12), a channel wherein the channel comprises a first end connected to the saddle and a second end, a tissue clamp (168 and 171) positioned around the channel, and a flange (170) formed adjacent to the second end of the channel, the method steps comprising engaging the channel of the coupler, making an incision into the blood vessel (col. 26, ll. 5-8), delivering a portion of the coupler including the fixed saddle into the blood vessel through the incision, securing the saddle to the blood vessel, and conforming the tissue clamp to the fixed saddle (fig. 10 or 11). Gifford fails to disclose the step of bending the tissue clamp away from the saddle and then releasing the clamp so that it conforms to the fixed saddle and instead discloses a clamp (168, 171) which

must be plastically deformed by advancement of a pusher member in order to conform to the fixed saddle.

5. It is well known in the art to employ clamp members that are made from shape memory materials. Gifford discloses using shape memory materials for clamping members in other embodiments including those shown in figs. 32a-32d. Berg et al. also teaches initially holding a clamp away from another member of a connector that is seated within a vessel and eventually releasing the clamp so that it traps a vessel wall therebetween (fig. 10b to 10c). It would have been obvious to one skilled in the art to have modified the embodiment of figs. 9-12 of Gifford to use a shape memory material for the clamps and include the steps of bending the clamp away from the saddle and then releasing the clamp to conform to the saddle as taught by Berg et al. because such a modification can be considered a combination of prior art elements according to known methods to yield predictable results. Additionally, the use of a shape memory clamp obviates the need for a pusher.

6. **Claims 13-19, 22, and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berreklouw (WO 00/24339) in view of Akin et al. (US 6,458,140; "Akin") and Collito (US 3,254,650). Berreklouw discloses a method of connecting two conduits comprising the steps of positioning a first saddle disposed at a first end of a first coupler having a first channel within a first conduit so that a portion of the first coupler is positioned on an inside wall of the first conduit and another portion of the first coupler is positioned on an outside wall of the first conduit, positioning a second saddle disposed at a first end of a second coupler having a second channel within a second conduit so that a portion of the second coupler is positioned on an inside wall of the second conduit, and another portion of the second coupler is positioned on an outside wall of the second conduit, clamping the first conduit to the first saddle of the first coupler, clamping the second conduit to the second saddle of the second coupler and

connecting the first and second coupler (see fig. 16 which shows the claimed structure positioned within two conduits with the wall of each conduit clamped between two portions a coupler). Berreklouw fails to disclose a first flange on a second end on the first coupler in alignment with a second flange on a second end on a second coupler wherein the method includes mating surfaces of the couplers and crimping a clamping ring around the flanges to secure them to each other, the first and second flanges being separated from the first and second conduits, respectively.

7. However, Akin et al. teaches that it is well known to provide a longer flow channel between two vessels that are being joined by a side-to-side anastomosis. Akin et al. discloses a pair of couplers used during an anastomosis procedure, wherein the couplers have portions which are spaced from their respective conduits (see for example figs. 9-11b) due to the length of the portions of the couplers extending between the two vessels being joined (compared to embodiment shown in fig. 7d). These lengthened portions together form a flow channel or shunt. It would have been obvious to one skilled in the art to have modified Berreklouw to increase the length of the couplers so that they form a flow channel as taught by Akin et al. Akin et al. teaches providing a ring (122; fig. 11b) around the mating surfaces of the couplers but does not disclose providing two flanges on the couplers and crimping a clamping ring around the flanges. However, clamping rings around mating flanges on the mating ends of two couplers is a well known technique for joining two conduits together as illustrated by Collito (see fig. 2-5; “ring ‘48”; col. 4, ll. 40-45). It would have been well within the purview of one skilled in the art to change the mating structure of the device of Berreklouw to increase the length of the couplers such that the two vessels are spaced apart and a longer flow channel is formed between them as taught by Akin et al. as well as adding mating flanges at the couplers’ second ends held together by a clamping ring as taught by Collito as such a modification would have been considered a

substitution of one known method of coupling two conduits for another known method of coupling two conduits. Furthermore, it is well known to crimp down a clamping ring to ensure that the ring will not be displaced.

8. Regarding claims 14 and 15, the method includes making a first incision and positioning the first saddle within the first conduit (p. 20, ll. 25-27). Berreklouw only expressly discloses making one incision (although two holes are shown in fig. 16) but because claims 15 and 14 each depend from 13, the designation of which conduit, saddle, and coupler is "first" and which is "second" can be changed so that the incision is made in the first or the second conduit.

9. Regarding claims 16 and 17, the step of clamping the first conduit to the first saddle comprises the step of heating a first tissue clamp to a transition temperature such that the first tissue clamp secures the first conduit between the first tissue clamp and saddle (p. 10, line 24 – p. 11, line 4, and p. 21, ll. 25 - p. 22, ll. 4, which discloses that the flanges of the devices of Berreklouw may be shape memory such that, when heated, they change configuration, locking the device in place).

10. Regarding claims 18 and 19, Berreklouw discloses legs formed on the saddles that are bent outward (extended in an outward direction) so that the first and second conduits are secured between the first saddle and coupler and the second saddle and coupler, respectively.

11. Regarding claim 22, Berreklouw fails to disclose connecting the first and second couplers before the steps of positioning the first and second saddle in the first and second conduit, respectively. However, Berreklouw does disclose that the two couplers could be made as an integral piece, which would result in the two couplers being connected before the first and second saddles are positioned within the first and second conduits. Furthermore, applicant has not disclosed any advantage gained, purpose served, or problem solved by joining the couplers together before the positioning step as opposed to joining the couplers after the positioning

step. One skilled in the art would have expected either order of the steps to perform the function of joining two conduits together equally well. Therefore, it would have been prima facie obvious to modify Berreklouw to connect the first and second couplers before the steps of positioning the first and second saddles in the first and second conduits because such a modification would have been considered a mere design consideration that fails to patentably distinguish the claimed invention from the prior art of Berreklouw.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

DETAILED ACTION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 11/12/2008

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731